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JC658 U.S. PTO  
05/28/99

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 62386

Hon. Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

JC649 U.S. PTO  
09/322579  
05/28/99

Sir:

1. This is a request for filing a:

(X) Continuation-in-part Application Under 37 CFR §1.53(b)

of pending prior application no. 08/798,516 filed on February 10, 1997 for DEVICE  
AND METHOD FOR ELIMINATING ADIPOSE LAYERS BY MEANS OF LASER  
ENERGY wherein the inventors are:

Cesare PAOLINI  
Maurizio MAIDA  
Fabrizio MENCARELLI

Using the enclosed specification of 16 pages and 20 claims.

The entire disclosure of the above mentioned pending prior application, is considered to be part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

2. Prior Application Information: Examiner: R. Nasser  
Group/Art Unit: 3736

3. X The filing fee is calculated below:

CLAIMS AS FILED, LESS ANY CLAIMS CANCELED BY AMENDMENT

	<u>FILED</u>	<u>EXTRA</u>	<u>RATE</u>	<u>FEE</u>
Total claims	20	0	\$22/\$11	\$0.00
Independent Claims	3	0	\$82/\$41	\$0.00

Multiple Dependant Claims No

Basic Filing Fee: \$ 380.00

Total Filing Fee: \$380.00

4. X The Commissioner is hereby authorized to charge any fees which may be required, or to credit any overpayment to our Deposit Account No. 13-0410.
5. X A check in the amount of \$ 380.00 is enclosed.
6.    Cancel claims
7. X Amend the specification by inserting before the first line the sentence:  
-- This is a continuation-in-part of application Serial No. 08/798,516 filed February 10, 1997, and the entire disclosure of this prior application is considered to be part of the disclosure of the accompanying application and is hereby incorporated by reference therein.--
8. X Formal drawings are enclosed.  
[Total Sheets: 1]
9. X The prior application is assigned to EL.EN. S.p.A. as recorded under Reel 8459 and Frame 0800 . A copy of this assignment is enclosed and this assignment carries over to the present application.
10. X Oath or Declaration [Total Pages: 3 ]
- a. X Newly Executed (original or copy)
- b.    Copy from a prior application (37 C.F.R. § 1.63(d))
11. X Any Convention priority claimed in the parent application is hereby claimed for this application.

12. ☐ A preliminary amendment is attached.
13. ☒ Small Entity status as claimed in the parent application is still proper and hereby claimed for this application. Another Small Entity document is enclosed.

14. ACCOMPANYING APPLICATION PARTS

- ☐ English Translation Document  
☐ Information Disclosure Statement/PTO Form 1449  
☐ Copies of IDS Citations  
☒ Return Receipt Postcard (MPEP 503)  
☐ Certified Copy of Priority Document  
☐ Request for Reconsideration  
☒ Other Appendix

15. ☒ CORRESPONDENCE ADDRESS BELOW:

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Name: Theobald Dengler

Reg. No.: 34,575

Signature: *Theobald Dengler* Date: May 28, 1999

TD:tf  
62386.6

DATED: May 28, 1999  
SCARBOROUGH STATION  
SCARBOROUGH, NEW YORK 10510-0827

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS EXPRESS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON, D.C. 20231, No. EL314932518US ON May 28, 1999

McGLEW AND TUTTLE, P.C., SCARBOROUGH STATION,  
SCARBOROUGH, NEW YORK 10510-0827

By: *Jonidunn Forte* Date: May 28, 1999

McGLEW AND TUTTLE, P.C.

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KRISTINA M. GRASSO, PATENT AGENT

Hon. Commissioner of Patents  
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Washington, D.C. 20231

Re: ATTORNEY DOCKET: 62386

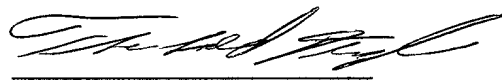
Sir:

Attached please find the complete application papers and fees in the above-identified application which are being placed in the U.S. Mail today, May 28, 1999, as Express Mail number EL314932518US.

A copy of the Express Mail receipt is also attached.

Respectfully submitted  
for Applicant(s),

By:



Theobald Dengler  
Reg. No. 34,575  
McGLEW AND TUTTLE, P.C.

TD:tf

Enclosures - Complete Application Papers and Fees  
- Copy of Express Mail Receipt

DATED: May 28, 1999  
SCARBOROUGH STATION  
SCARBOROUGH, NEW YORK 10510-0827  
(914) 941-5600

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH  
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McGLEW AND TUTTLE, P.C., SCARBOROUGH STATION,  
SCARBOROUGH, NEW YORK 10510-0827

BY: *Jon'Ann Forte* DATE: May 28, 1999

62386.7

ATTORNEY DOCKET NO. 62386

Applicant: PAOLINI et al.

Serial No.:

Filed:

For: DEVICE AND METHOD FOR ELIMINATING ADIPOSE LAYERS BY MEANS OF LASER ENERGY

VERIFIED STATEMENT (DECLARATION) CLAIMING  
SMALL ENTITY STATUS  
(37 CFR 1.9(f) and 1.27 (c)) SMALL BUSINESS CONCERN

I hereby declare that I am

- ☐ the owner of a small business concern identified below:  
☒ an official of the small business concern empowered to act on  
behalf of the concern identified below

NAME OF CONCERN EL.EN. S.p.A.

ADDRESS OF CONCERN Via G.da S. Giovanni No. 10, 50141 FIRENZE, Italy

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees to the United States Patent and Trademark Office, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract of law have been conveyed to the remain with the small business concern identified above with regard to the invention, entitled DEVICE AND METHOD FOR ELIMINATING ADIPOSE LAYERS BY MEANS OF LASER ENERGY by inventor(s): Cesare PAOLINI, Maurizio MAIDA, Fabrizio MENCARELLI described in

- ☒ the specification filed herewith  
☐ application serial no. \_\_\_\_\_, filed \_\_\_\_\_,  
☐ patent no. \_\_\_\_\_, issued \_\_\_\_\_.

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below\* and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9 (c) if that person made the invention or by any concern which would not qualify as small business concern under 37 CFR 1.9 (d) or a nonprofit organization under 37 CFR 1.9 (e). \*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME \_\_\_\_\_  
ADDRESS \_\_\_\_\_  
[ ] SMALL BUSINESS CONCERN [ ] NONPROFIT ORGANIZATION

NAME \_\_\_\_\_  
ADDRESS \_\_\_\_\_  
[ ] SMALL BUSINESS CONCERN [ ] NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING CLEMENTI Gabriele  
TITLE OF PERSON OTHER THAN OWNER President  
ADDRESS OF PERSON SIGNING Via L. Bardelli 27 - 50139 FIRENZE Italy

SIGNATURE  DATE May 21, 1999

Docket No. 62,386

***Device and Method for Eliminating Adipose  
Layers by Means of Laser Energy***

**FIELD OF THE INVENTION**

The present invention relates to a device for eliminating adipose layers and to an associated technique for carrying out this elimination using the device.

**BACKGROUND OF THE INVENTION**

5       The reduction of subcutaneous adipose layers constitutes one of the most important areas of aesthetic treatments.



Two techniques currently exist for this purpose. The first technique, known as liposuction, consists of introduction into the adipose layers of probes roughly 5 mm in diameter through holes made in the skin of the patient undergoing treatment, for suction and removal of fat. This technique has a number of disadvantages, such as the creation of a lack of homogeneity in the form of depressions in the zone of insertion of the probe which are visible from the outside, as well as excessive bleeding of the patient undergoing treatment. Furthermore, both the cells of fat and the stroma are sucked out non-selectively.

The second technique utilizes subcutaneous ultrasonic probes to rupture the membrane of the adipose cells, thus causing the escape of liquid which then has to be sucked out subsequently. In this case, suction of the stroma is not brought about and bleeding is therefore more limited. However, the disadvantage of the lack of homogeneity of the treatment remains.

## SUMMARY AND OBJECTS OF THE INVENTION

The primary aim of the present invention is to produce a device and an associated method for eliminating adipose layers which do not have the disadvantages mentioned above.

In particular, a first aim of the present invention is the production of a device and a method which allow uniform treatment.

A further aim is the production of a device and a method which allow selective elimination of the adipose cells without damaging the stroma.

Yet another aim of the present invention is the production of a device and a method which eliminate the problem of bleeding and which reduce the dimensions of the holes for insertion of the probes.

These and other aims and advantages, which will be clear to experts in the field from reading the text which follows, are obtained essentially with a device which comprises a first laser source, optical fiber conveying means for conveying the laser beam emitted by said first source, and a hollow needle for guiding the fiber. The fiber ends in the vicinity of the end of the needle. A laser source generates a laser beam through the optical fiber with an intensity and a wavelength for liquefying, and maintaining liquid, the adipose cells. The intensity and wavelength of the laser beam ruptures membranes of the adipose cells and maintains collagen in the adipose layer substantially unaltered or undamaged. Blood vessels in the adipose layer are either also substantially undamaged, especially the large blood vessels, or any blood vessels that are damaged are cauterized, especially the small blood vessels.

With this device, it is possible to implement a method for the reduction of subcutaneous adipose layers, on the basis of introducing into the subcutaneous adipose layers a laser beam at an intensity and at a wavelength which are such that the lipolysis of the adipose cells is brought about, that is a rupturing of the membranes of the cells themselves, with consequent transformation of the adeps into a liquid substance which is then sucked out or preferably left in place in order to be drained by the lymphatic system and by the action of the phagocytes of the patient. In addition to a clear reduction in traumatism and greater selectivity of the method implemented in this

manner in comparison with the liposuction system, the advantage is also obtained that the energy of the laser beam can be used to cauterize the small blood vessels which may be damaged by the insertion of the needle into the adipose layers. Loss of blood is thus virtually completely eliminated.

5 Attached as an appendix to this application is an electronic microscope image of tissue treated with the method of the invention. There are three main elements in the area treated with the method of the invention:

- A, a mass of adipose cells still to be subject to lysis;
- 10 B, hollow spaces where the adipose cells have been ruptured and the liquid generated by lipolysis has been removed by suction;
- C. a structure of collagen fibers both in the space where adipose cells are still present as well as in the area where the adipose cells have been ruptured and removed.

15 The most important aspect to be highlighted in the area treated by the present invention, and shown in the microscope image, is the fact that the collagen fibers remain intact even where the adipose layer has been removed. The presence of the collagen structure is very important for the reconstruction of healthy (non-fatty) tissue in the area where the adeps has been removed.

20 Usual liposuction techniques remove by suction entire pieces of adipose tissue and together therewith they also remove portions of blood vessels and collagen fibers. Thus present liposuction intervention is heavily invasive. The area under the skin where the collagen fibers have been removed together with the adipose tissue shows

depressions and "sinkings" which are highly unaesthetical. Reconstruction of healthy (non-adipose) tissue in these areas is slow and unsatisfactory, due to the reduced vascularization and to the absence (or reduced presence) of collagen.

The method of the present invention is novel and advantageous over the art because it overcomes the above mentioned drawbacks. The method is mainly characterized in that the adipose tissue is removed by lysis, i.e. by rupturing the membranes of the cells forming the adipose layer. As a consequence, the adipose tissue is transformed into a liquid. The liquid thus obtained may be partially or totally suctioned away by means of a vacuum pump, quite in the same way as in the usual techniques. The difference is, however, the material removed through the suction cannula is substantially liquid and a much reduced impact on the patient is obtained. It is obviously easier and less painful to suck a liquid (generated by lipolysis) than pieces of adipose tissue which are solid. The collagen fibers and blood vessels are not damaged by the lysis effect of the laser and remain intact. The subsequent suction does not suck the collagen fibers nor the blood vessels away, as it happens in the traditional liposuction techniques. Subsequent recovery of the healthy tissue is easier.

As an alternative the liquid substance is left inside the body of the patient. In this case the liquid obtained by lysis of the adipose cells is slowly re-absorbed through the organism of the patient himself, namely through action of the lymphatic system and the phagocytes. This second method is slower than the former one, but is even less invasive and less traumatic.

In practice, the needle is borne by a hand unit which, in order to be more easily

maneuverable, is inclined in relation to the needle.

In addition to a laser source which emits at a wavelength and at a power which are such that lipolysis is brought about, it is possible, with the same optical fiber, or with an additional optical fiber guided in the same needle, to convey into the adipose layers a beam of visible light which makes possible transcutaneous vision during implementation of the method.

The various features of novelty which characterize the invention are pointed out with particularity in the claims annexed to and forming a part of this disclosure. For a better understanding of the invention, its operating advantages and specific objects attained by its uses, reference is made to the accompanying drawings and descriptive matter in which preferred embodiments of the invention are illustrated.

## BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

Fig. 1 is a diagram of the device;

Fig. 2 is an enlarged longitudinal section view of the hand unit of the device in Fig. 1;

Fig. 3 is an enlarged view of the point of the needle, and

Fig. 4 is a view of the device being used in an example of application.

## DESCRIPTION OF THE PREFERRED EMBODIMENT

With reference initially to Fig. 1, the device comprises a laser source 1 of the

NdYAG type, with which an optical fiber 3 is associated, which conveys the energy of the source 1 toward a hand unit 5 equipped with a hollow guide needle 7 with a beveled end (Fig. 3). The needle has an external diameter of, for example, roughly 1 mm. The terminal end 3A of the optical fiber 3 ends at the point of the needle. The laser source 1 generates a laser beam through the optical fiber 3 with an intensity and a wavelength for liquefying, and maintaining liquid, the adipose cells. The intensity and wavelength of the laser beam ruptures membranes of the adipose cells and maintains collagen in the adipose layer substantially unaltered or undamaged. Blood vessels in the adipose layer are either also substantially undamaged, especially the large blood vessels, or any blood vessels that are damaged are cauterized, especially the small blood vessels.

In the example illustrated, the needle has an inclination in relation to the hand unit 5 of roughly 10-30 degrees and preferably 15-20 degrees to facilitate its use.

In Fig. 2, a possible system of fixing the fiber 3 can be seen, which comprises an elastic sleeve 11 accommodated in a seat 13, through which the fiber 3 passes and which is clamped by means of a threaded ring nut 15.

In the example illustrated, the device comprises a second laser source 21 which emits radiation in the visible range which is conveyed by means of a second optical fiber 23 to a connector 25, in which the visible radiation emitted by the laser 21 is introduced into the fiber 3. In this manner, the optical fiber 3 conveys to the point of the needle 7 a laser beam in the visible range also which allows the operator, in reduced ambient light, to follow accurately (by transcutaneous vision permitted by the

transparency of the skin) the position of the end of the fiber and therefore to control the instantaneous point of application of the laser energy generated by the source 1.

The laser source 1 emits a beam which is preferably pulsed, at a wavelength between 0.75 and 2.5 micrometers, for example at 1.06 micrometers, with an energy level between 30 and 300 mJoules per pulse. The wavelength is preferably between 0.8 to 1.1 micrometers and the pulse frequency is between 10 and 60 Hz, preferably between 30 and 50 Hz and most preferably around 40 Hz.

The device described above is used by inserting the fiber subcutaneously into the patient, in the adipose layer to be eliminated. The end of the fiber 3 thus comes directly into contact with the adipose layer. The laser beam, in the appropriate dosage, brings about the rupturing of the membranes of the adipose cells and at the same time cauterizes the very small veins contained in the stroma, which can be easily damaged by the penetration of the needle 7. In this manner, the adeps becomes liquid and at the same time a local hemostasis is created. The liquefied fat is then absorbed by the body by lymphatic drainage and the action of the phagocytes, while subsequent intervention, similar to that carried out in the case of treatment with ultrasonic probes, to remove the liquefied fat is also possible.

In practice, the needle 7 is provided with a skin cutting tip and used to cut or pierce the skin of the patient. The needle is initially inserted subcutaneously and is then moved forward and backward by the operator to irradiate the adipose cells and cause lipolysis of the adipose layer and rupture membranes of the cells forming the adipose layer, thus transforming adeps forming the adipose layer into a liquid

substance. The laser beam is generated and the irradiating performed to maintain the adipose cells as a liquid substance. The time which is necessary for the above depends on the characteristics of the tissue which is easily determined by the operator. Typically, to achieve the lipolysis of an adequate quantity of adipose cells, treatment with an energy level of 100 mJoules for a time of 200 microseconds per pulse is appropriate. The needle is kept in each penetration hole for a few minutes.

The liquid substance can then be removed by suctioning said liquid substance away from the adipose layer through a passage in the device or by another tool inserted through the skin of the patient. In another embodiment of the present invention the needle is removed from the patient leaving the liquid substance in the patient. The liquid substance is then left to be absorbed through elements of the patient adjacent the adipose cells, namely through the lymphatic system and phagocytes of the patient.

The movement of the point of the needle is easily controlled by means of the transcutaneous vision allowed by the visible laser beam generated by the second source 21. Lipolysis action is thus brought about in a certain portion of tissue. By extracting the needle and inserting it subcutaneously in an adjacent position, a subsequent portion of tissue is treated. From one and the same entry hole, the needle 7 can be inserted in various radial directions, treating an entire area of the tissue, as can be seen in Fig. 4, where 31 indicates in broken lines as a guide the insertion lines of the needle 7.

The end part of the needle 7 can be knurled in order to cause, during penetration of the adipose layers, a rupturing of the adipose cells and therefore in order to obtain greater effectiveness of treatment. In Fig. 3, the knurling is indicated



diagrammatically by Z.

It is intended that the drawing shows only an example given only by way of practical demonstration of the invention, it being possible for the invention to vary in form and arrangement without moreover leaving the scope of the concept which forms the invention itself.

While specific embodiments of the invention have been shown and described in detail to illustrate the application of the principles of the invention, it will be understood that the invention may be embodied otherwise without departing from such principles.

## WHAT IS CLAIMED IS:

1. A method for the removal of subcutaneous adipose layers, the method comprising the steps of:

providing a hollow needle with a tip;

providing a laser source with emitting characteristics for generating a laser beam having an intensity and a wavelength for causing lipolysis of adipose cells;

generating a laser beam with said laser source;

arranging an optical fiber inside said needle with one end of said optical fiber adjacent to said tip of said needle and with another end of said fiber connected to an output of said laser source;

piercing the skin of a patient and bringing said needle tip into a subcutaneous adipose layer of the patient;

irradiating said adipose layer with said laser beam to cause lipolysis of said adipose layer and rupturing membranes of cells forming the adipose layer, thus transforming adeps forming said adipose layer into a liquid substance.

2. The method in accordance with claim 1, further comprising:

suctioning said liquid substance away from the adipose layer.

3. The method in accordance with claim 1, further comprising:

removing said hollow needle from the patient leaving said liquid substance in

place, said liquid substance being subsequently absorbed by the organism of the patient.

4. The method in accordance with claim 1, wherein:

said tip of said needle includes a sharp edge;

said piercing of the skin is performed with said needle.

5. The method in accordance with claim 4, further comprising:

suctioning said liquid substance away from the adipose layer.

6. The method in accordance with claim 4, further comprising:

removing said hollow needle from the patient leaving said liquid substance in place, said liquid substance being subsequently absorbed by the organism of the patient.

7. The method in accordance with claim 1, wherein:

said generating of said laser beam and said irradiating is performed to cauterize blood vessels in the adipose layer damaged by said irradiating.

8. The method in accordance with claim 1, further comprising:

irradiating the adipose layer with another laser beam to provide transcutaneous vision.

9. The method in accordance with claim 1, wherein:

said generating is performed to generate said laser beam as a pulsed laser beam.

10. The method in accordance with claim 1, wherein:

said generating is performed to generate said laser beam as a pulsed laser beam with a wavelength 0.75 and 2.5 micrometers, and with an energy level between 30 and 300 mjoules per pulse.

11. The method in accordance with claim 1, wherein:

said generating is performed to generate said laser beam as a pulsed laser beam with a pulse frequency between 10 and 60 Hz, with a wavelength between 0.75 and 2.5 micrometers, and with an energy level between 30 and 300 mjoules per pulse.

12. The method in accordance with claim 1, wherein:

said pulse frequency is between 40 and 50 Hz.

13. A method for treating adipose cells in a patient, the method comprising the steps of:

providing a hollow needle with a tip and an optical fiber inside said needle with one end of said optical fiber adjacent to said tip of said needle;

generating a laser beam through said optical fiber with an intensity and a wavelength for liquefying, and maintaining liquid, the adipose cells;

moving said tip of said needle into a subcutaneous adipose layer of the patient;  
irradiating adipose cells in the adipose layer with said laser beam from said  
optical fiber to transform the adipose cells into, and maintain the adipose cells as, a  
10 liquid substance.

14. The method in accordance with claim 13, wherein:

said generating of said laser beam and said irradiating is performed to rupture  
membranes of the adipose cells without substantially damaging collagen in the adipose  
layer.

15. The method in accordance with claim 13, wherein:

said generating of said laser beam and said irradiating is performed to rupture  
membranes of the adipose cells and maintain both collagen and blood vessels in the  
adipose layer substantially unaltered.

16. The method in accordance with claim 13, further comprising:

suctioning said liquid substance away from the adipose layer.

17. The method in accordance with claim 13, further comprising:

removing said needle from the patient leaving said liquid substance in the  
patient;

absorbing said liquid substance through elements of the patient adjacent the

5 adipose cells.

18. The method in accordance with claim 17, wherein:

said absorbing is through a lymphatic system and phagocytes of the patient.

19. The method in accordance with claim 13, further comprising:

providing said needle with a skin cutting tip;

cutting a skin of the patient with said skin cutting tip of said needle.

20. A device for treating adipose cells in a patient, the device comprising:

a hollow needle with a tip;

an optical fiber inside said needle with one end of said optical fiber adjacent to  
said tip of said needle;

5 a laser source generating a laser beam through said optical fiber with an  
intensity and a wavelength for liquefying, and maintaining liquid, the adipose cells, said  
intensity and wavelength of said laser beam rupturing membranes of the adipose cells  
and maintaining collagen in the adipose layer substantially unaltered.

## ABSTRACT OF THE DISCLOSURE

A device and method for the removal of subcutaneous adipose layers with a laser source, optical fiber for conveying the laser beam emitted by the first source and a hollow needle for guiding the fiber. The fiber ends in the vicinity of the end of the needle. The laser beam is generated with an intensity and a wavelength for liquefying, and maintaining liquid, the adipose cells. The laser beam from the optical fiber irradiates adipose cells in the adipose layer to transform the adipose cells into, and maintain the adipose cells as, a liquid substance.

62386.1



APPENDIX



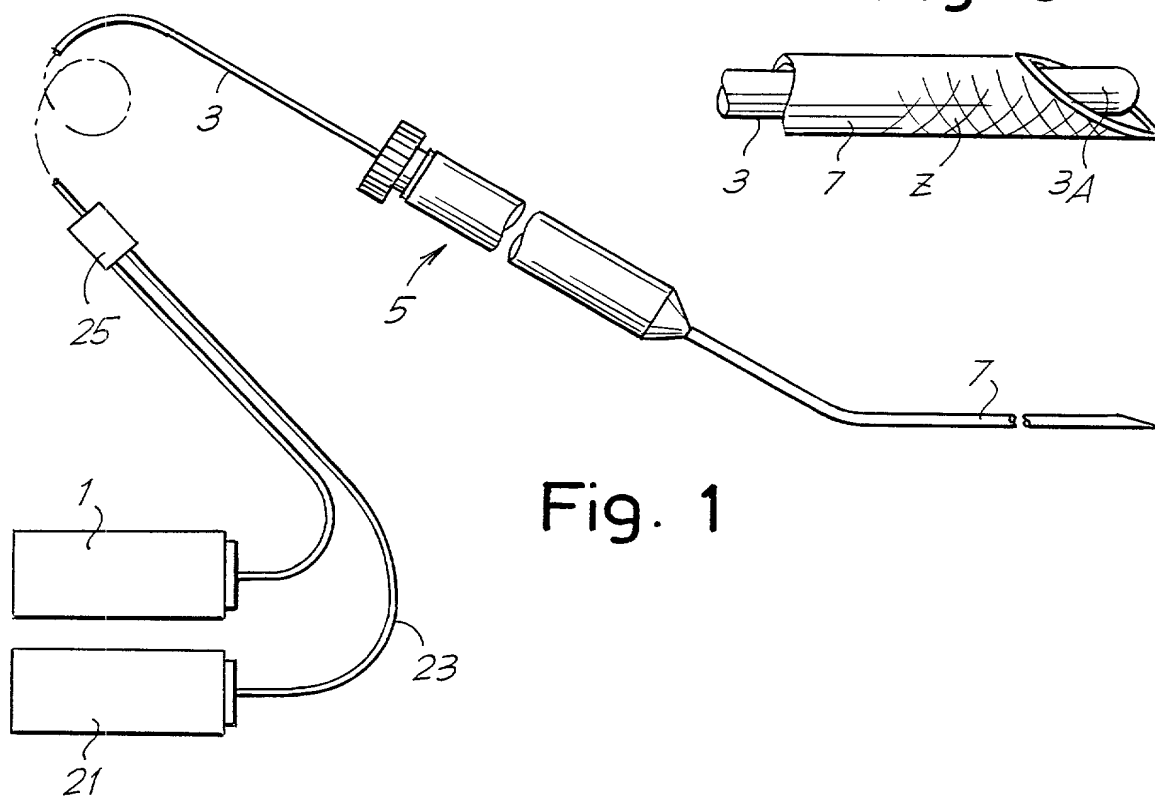


Fig. 3

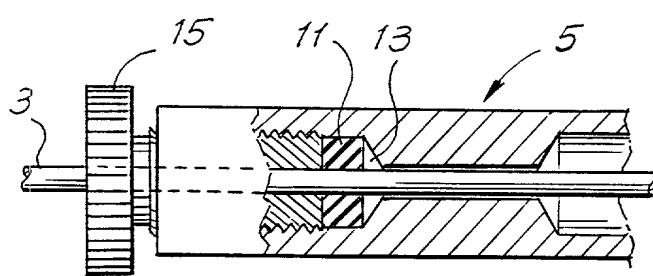
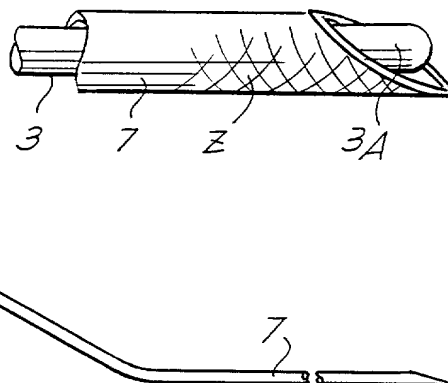
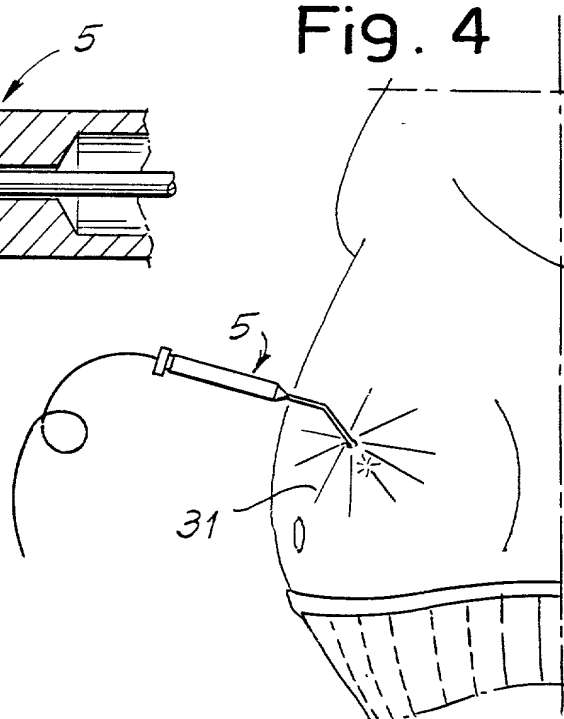


Fig. 4



## DECLARATION FOR PATENT APPLICATION

Docket No.62386

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: DEVICE AND METHOD FOR ELIMINATING ADIPOSE LAYERS BY MEANS OF LASER ENERGY

the specification of which

(Check one) ☒ [X] is attached hereto.

☐ [ ] was filed on \_\_\_\_\_ as

Application Serial No. \_\_\_\_\_

and was amended on \_\_\_\_\_

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

FI/96/A/000025

(Number)

Italy

(Country)

13/Feb./1996

(Day/Month/Year filed)

Priority Claimed

YES

\_\_\_\_\_  
(Number)

\_\_\_\_\_  
(Country)

\_\_\_\_\_  
(Day/Month/Year filed)

\_\_\_\_\_  
(Number)

\_\_\_\_\_  
(Country)

\_\_\_\_\_  
(Day/Month/Year filed)

(Number)

(Day/Month/Year filed)

I hereby claim the benefit under Title 35, United States Code, 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code 112. I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

08/798,516  
(Application Serial No)

February 10, 1997  
(Filing Date)

Pending  
(Patented, Pending, Abandoned)

\_\_\_\_\_  
(Application Serial No)

\_\_\_\_\_  
(Filing Date)

\_\_\_\_\_  
(Patented, Pending, Abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: **John J. McGlew, Reg. 17,722; and/or John James McGlew, Reg. 31,903; and/or Hilda S. McGlew Reg. 30,295; and/or Theobald Dengler, Reg. 34,575; and/or Clario Ceccon, Reg. 19,268; and/or Kristina M. Grasso Reg. 39,205.**

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor Cesare PAOLINI

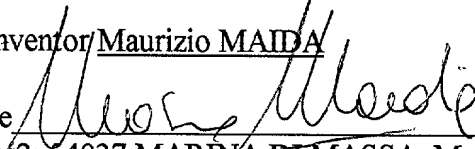
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Full name of fourth inventor \_\_\_\_\_

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Full name of fifth inventor \_\_\_\_\_

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→Inventor's signature \_\_\_\_\_

→Date \_\_\_\_\_

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